



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

91612d

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6010

August 8, 2001

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Ms. Caron Wendell
President
Lucy's Ravioli Kitchen, Inc.
830 State Road (Route 206)
Princeton, New Jersey 08540

01-NWJ-34

Dear Ms. Wendell:

We inspected your firm, located at 830 State Road, Princeton, NJ, on June 26, 2001, and found that you have a serious deviation from the Seafood HACCP regulations, Title 21, Code of Federal Regulations, Part 123. This deviation causes your shrimp and scallop ravioli product to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov. This deviation and the need for its correction were brought to your attention during previous inspections in 1999 and 2000 and in an untitled letter dated September 8, 1999.

The deviation was as follows:

You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for your frozen shrimp and scallop ravioli to control the food safety hazard of sulfites in the shrimp ingredient.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within three weeks of your receipt of this letter. Your response should outline the specific things you are doing to correct this deviation. You may wish to include in your response documentation such as a revised HACCP plan, revised monitoring procedures, or other useful information that would assist us in evaluating your correction. If you cannot complete the correction before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

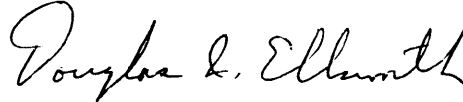
Lucy's Ravioli Kitchen, Inc.
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You may send your response to: U.S. Food & Drug Administration, 10 Waterview
Boulevard, 3rd Floor, Parsippany, New Jersey 07054, Attn: Sarah A. Della Fave,
Compliance Officer.

Sincerely,

A handwritten signature in black ink, reading "Douglas I. Ellsworth". The signature is written in a cursive style with a large initial 'D'.

Douglas I. Ellsworth
District Director